

Guidance for Industry and FDA Staff

# **Dental Impression Materials - Premarket Notification**

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**U.S. Department Of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Dental Devices Branch  
Division of Dental, Infection Control, and General Hospital Devices  
Office of Device Evaluation**

# Preface

## Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dr. Susan Runner, FDA/CDRH, 9200 Corporate Blvd., HFZ-480, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Dr. Susan Runner at (301) 827-5283.

## Additional Copies

World Wide Web/CDRH home page: <http://www.fda.gov/cdrh>, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2203 prompted for the document shelf number.

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# **Guidance for the Preparation of Premarket Notifications for Dental Impression Material**

## **1.0 INTRODUCTION**

The purpose of this document is to provide guidance to the manufacturers of dental impression material on the information desired for a more thorough and consistent preparation of a Premarket Notification submission (510(k)).

The development of this document is based on information recommended for a complete and adequate review by the Dental Devices Branch. The use of this document for the preparation of a 510(k) for dental impression material does not ensure FDA clearance of a device, and certain 510(k) submissions may require additional information not contained in this document. However, use of this document will ensure that the basic elements are present to conduct an evaluation of substantial equivalence..

This guidance is subject to revision depending upon development of new technological information and/or changes in regulatory requirements.

### **Standards**

Medical device manufacturers may elect to rely upon recognized consensus standards during the design and testing phase of their devices. We recognize that consensus standards, such as ISO standards, undergo periodic review and are subject to revision. FDA has published a document entitled “Guidance on the Recognition and Use of Consensus Standards” which provides guidance to industry and FDA reviewers on the use of recognized consensus standards, including declaration of conformity to the standards, during the evaluation of premarket submissions (Federal Register/Volume 63, No. 37/Wednesday, February 25, 1998). This document and related lists of recognized standards are on the Internet at FDA’s web site “<http://www.fda.gov/cdrh>”.

## **2.0 GENERAL INFORMATION**

**510(k) Summary or 510(k)Statement.** In accordance with the Safe Medical Devices Act of 1990 and 21 CFR Part 807.87(h), the applicant must submit either: (1)A summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (i.e., a “510(k) summary”); or (2)a statement that safety and effectiveness information will be made available to interested persons upon request (i.e., a “510(k) statement”). The summary or statement should be clearly identified as a “510(k) summary” or a “510(k) statement”.

**Truthful and Accurate Statement.** As required by 21 CFR Part 807.87(j), the applicant must also provide a Truthful and Accurate Statement that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

**Indications for Use Form.** On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked “Indications for Use” the indications(s) for use of their device and the device trade name.

### **The New 510(k) Paradigm**

On March 19, 1998, new procedures for the submission of 510(k)’s became effective. These procedures are collectively called the “New 510(k) Paradigm.” More information on the New 510(k) Paradigm is available on the Internet at the following FDA web site: <http://www.fda.gov/cdrh/ode/parad510.pdf>.

## **3.0 DEVICE DEFINITION**

**Dental Impression Material** is a class II device composed of materials such as alginate or polysulfide intended to be placed on a preformed impression tray and used to reproduce the structure of a patient’s teeth and gums. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures. See 21 CFR Part 872.3660. (FDA Product Code “ELW”)

## **4.0 PRODUCT DESCRIPTION**

- State the classification name and the trade name of the impression material.
- Submit a detailed description of your product and its indication for use.
- Clearly specify whether a single paste or two paste (base/catalyst) system is employed, and all the accessories of the system.
- Provide a descriptive or table comparison of the similarities and differences to a legally marketed predicate material in terms of intended use, chemical composition, physical characteristics and mechanical properties, safety and effectiveness.

## **5.0 CHEMICAL IDENTITY**

- Provide the complete impression material formulation, identifying the individual chemical components by percentage, to a sum of 100%.
  - Note the function of each chemical constituent.
  - Do not omit any chemical component nor submit generalizations under vague description such as “polymer compound.”
  - Provide the specific chemical name, and not a proprietary or trade name, or abbreviated chemical name.
  - Disclose all the pigments or other colorants used in the formulation
  - Include the material safety data sheet (MSDS) for each chemical component, a diagram of the chemical structure and the molecular formula of the finished material, and the Chemical Abstracts Service (CAS) number if available.

## 6.0 PHYSICAL AND MECHANICAL PROPERTIES

The impression material should be compared to the predicate material in terms of:

- Method of manipulation
- Flow properties
- Viscosity
- Wetability
- Working time
- Setting reaction time
- Mechanical (compressive and tear) strength
- Working humidity
- Dimensional accuracy
- Stability
- Consistency
- Patient acceptability
- Safety (should not be toxic, carcinogenic, mutagenic, irritating, or sensitizing)
- Compatibility with the die and cast materials
- Keeping (storage) qualities
- Curve of the shrinkage.

If the physical properties of the impression material conform to a consensus standard for performance testing, the specific standard should be referenced as follows:

<u>Impression Material</u>	<u>ADA/ANSI Specification No.</u>
Alginate	#18
Biological Evaluation	#41
Elastomeric Material	#19
Impression Compound	#3
Impression Paste, Zinc Oxide-Eugenol	#16

A summary should be provided of the methodology and results of all bench testing that has been conducted. The quantitative test results for your materials testing should be compared to those of predicate impression materials.

## 7.0 BIOCOMPATIBILITY TESTING

Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The device materials should not, either directly or through the release of their material constituents: (1) Produce significant adverse local or systemic effects; (2) be carcinogenic; or (3) produce adverse reproductive and developmental effects. Therefore, evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials.

The ISO standard, ISO-10993, Part 1, uses an approach to test selection that is very similar to the Tripartite Guidance used in the past by FDA. It also uses a tabular format (matrix) for laying out the test requirements based on the various factors discussed above. The matrix consists of two tables, "Initial Evaluation Tests for Consideration" and "Supplementary Evaluation Tests for Consideration." To harmonize biological response testing with the requirements of other countries, FDA has recognized the ISO standard. Reviewers in the Office of Device Evaluation will accept data developed according to ISO-10993, Part 1, with the matrix as modified and presented in Blue Book Memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing."

Manufacturers are advised to begin discussions with the Dental Devices Branch prior to the initiation of expensive, long-term testing of any new device materials to ensure that the proper testing will be conducted, and to avoid unnecessary tests.

Biocompatibility testing is indicated when the product contains a "new" or nonconventional chemical component is added for which the safety or effectiveness of the resulting formulation is in question. A material may be considered new based upon several factors, such as methods of manufacture, sterilization, duration of body exposure, etc. The biocompatibility testing should be performed on the finished product, i.e., in a form as close as possible to what the patient will be exposed to.

This is a list of the minimum testing which should be addressed in a regulatory submission:

- In Vitro Cytotoxicity
- Ames Test for Mutagenicity
- Mucus Membrane Irritation (hamster's pouch)
- Sensitization Test in Guinea Pigs
- Carcinogenicity (if tumorigenic potential previously documented)



For details on how to conduct these tests, refer to an appropriate international standard such as: American National Standard/American Dental Association Document No 41 for Recommended Standard Practices for Biological Evaluation of Dental Materials, 1982; or ISO/TR: 1984(E), Biological Evaluation of Dental Materials, 1984.

## **8.0 LABELING**

It is important to the consumer that the labeling for the dental impression material bear clear, accurate, and complete information for use concerning any relevant materials, indications, method of preparation, hazards, contraindications, and precautions in their use. Additionally, there should be no unsupported performance claims nor unfounded claims of technological superiority over legally marketed impression materials.

As described in 21 CFR Part 801.109, labels should bear the statement “Caution: Federal law restricts this device to sale by or on the order of a dentist.” Also, instructions for use of the product should bear the date of the issuance or the date of the latest revision.

Include in the 510(k) submission the proposed package labels and labeling, including available promotion and advertising information. Labeling refers to the package label plus other written, printed, or graphic material that accompanies the device or that is placed on either the device or any of its wrappers or containers. Advertising may be considered labeling, especially if it accompanies the material. See sections 201(k) and (m) and 502(f)(1) and (2) of the Federal Food, Drug, and Cosmetic Act.

If you wish specific advice on the applicability to your device of the FDA labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Additionally, note the regulation titled “Misbranding by reference to premarket notification” (21 CFR Part 807.97).

## 9.0 CONTACT

Questions regarding this guidance should be addressed to:

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General information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet web site: <http://www.fda.gov/cdrh/dsma/dsmamain.html>.